

## REMARKS

Upon entry of the present amendment, claims 1, 27-29, and 31-33 are pending in the instant application. Claim 1 has been amended, and claim 26 has been cancelled without prejudice or disclaimer. Support for the claim amendments presented herein is found throughout the specification and in the claims as originally filed. For example, support for the amendment to claim 1 is found at least in the paragraphs on page 49; in the paragraph bridging pages 69-70 and in Figure 1A of the as-filed application. Accordingly, no new matter has been added the amendments presented herein.

### **Claim Objections**

The Examiner has objected to claim 1 as being informal. Claim 1 has been amended herein, and Applicant submits that the syntax of claim 1 has been improved. Withdrawal of this objection is, therefore, requested.

### **Claim Rejections Under 35 U.S.C. §112, First Paragraph**

Claims 1, 26-29 and 31-33 remain rejected under 35 U.S.C. §112, first paragraph as lacking written description and enablement.

Applicants traverse this rejection. Claim 1 has been amended to recite a method of inhibiting osteoclast-mediated bone resorption, comprising inhibiting an activity of a gene product encoded by osteoclast associated gene OC14 comprising the nucleotide sequence of SEQ ID NO: 50 by administering a compound that decreases the activity of said gene product by at least 10% in the presence of said compound, as compared to the activity of said gene product in the absence of said compound, and wherein said compound is an antibody or an antisense polynucleotide.

Applicants submit that the claimed methods are described in such a way as to demonstrate that the patentee was in possession of the invention at the time the instant application was filed. The claimed invention is based on the discovery by the inventors that the expression of the osteoclast-associated gene OC14 is up-regulated during RANKL-induced osteoclastogenesis. The inventors were the first to identify that osteoclast-mediated bone resorption can be inhibited by decreasing the expression of a gene product encoded by the osteoclast-related gene OC14.

The subject-matter of the pending claims as amended is literally described in the specification, *e.g.*, at pages 1-2 and at page 49. Moreover, the specification discloses that decreasing the expression of a gene product encoded by the osteoclast-related gene OC14 will inhibit osteoclast-mediated bone resorption. The specification also teaches that inhibition of the gene product encoded by OC14 is not limited by the particular type of compound that is used to produce the desired decrease in expression of the OC14 gene product.

Thus, the specification teaches one how to modulate osteoclast-mediated bone resorption and provides the necessary information to allow the skilled artisan to do so, namely, by targeting and inhibiting the activity of the OC14 gene product. Studies by Richard Battaglino and Philip Stashenko, two of the named inventors of the instant application, have demonstrated the ability of siRNA polynucleotides to inhibit osteoclast differentiation and resorption activity. (*See* Battaglino et al., *Bone*, vol. 42: 180-192 (2008) at pages 186-189 and in Figures 8-9, previously submitted to the Office). In particular, these studies confirm that the use of antisense polynucleotides specific for the OC14 gene (referred to as the NHA-oc/NHA2 gene in this paper) resulted in a significant inhibition, *i.e.*, approximately 60%, of osteoclast resorption activity. The skilled artisan does not have to establish that a product of the OC14 gene is responsible for bone resorption and could practice the claimed methods without undue experimentation.

The disclosure in the specification as originally filed does provide a method of successfully inhibiting osteoclast-mediated bone resorption. Accordingly, Applicants submit that the amended claims satisfy all requirements of the first paragraph of 35 U.S.C. §112. As such, these rejections should be withdrawn.

## CONCLUSION

On the basis of the foregoing amendment and remarks, Applicants respectfully submit, that the pending claims are in condition for allowance. If there are any questions regarding this amendment and/or these remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

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